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| 10/658,736 | 09/09/2003 | Alan Shluzas | 1291.1138101 | 3377 |
| 33469 7590 08/06/2009 CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420 | | | | |
| EXAMINER WOODALL, NICHOLAS W | | | | |
| ART UNIT 3775 | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/658,736

Applicant(s)

SHLUZAS ET AL.

Examiner

Nicholas Woodall

Art Unit

3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to applicant's amendment/arguments filed on 04/03/2009.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 20-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathews (U.S. Patent 6,033,406) in view of Haider (U.S. Patent 6,485,494) and Foley (U.S. Patent 5,792,044) and Davison (U.S. Publication 2001/0011170).

Mathews discloses a method of treating the spine via a posterior approach comprising placing a fusion device, i.e. a bone graft, in an intervertebral disc space between a first vertebra and a second vertebra in combination with a spinal fixation system and placing a bone growth material, i.e. osteoinductive proteins or morphogenic proteins, on the fusion device inserted into the intervertebral disc space. Mathews fails to disclose the method further comprising the steps of performing a multi-level fixation procedure, i.e. the fixation of more than one spinal segment, the spinal fixation system comprising fasteners and an elongated member, advancing a decompression tool into the surgical site to perform a decompression procedure, i.e. a laminectomy and facetectomy, on the vertebrae, and inserting an access device in a first configuration through an incision of the skin until a distal portion is located adjacent the spine,

actuating the access device to a second configuration having an enlarged cross-sectional area at the distal portion spanning at least a portion of the multiple vertebrae, and performing the surgical procedures through the access device. Haider teaches a method comprising the steps of performing a multi-level fixation in order to fix multiple joints of the spine (column 6 lines 1-5). Foley teaches a method comprising the step of inserting a decompression tool into a surgical site to perform a decompression procedure on the vertebrae in order to reduce pressure on the spinal cord. Davison teaches a method comprising the steps of inserting an access device in a first configuration through an incision of the skin until a distal portion is located adjacent the spine, actuating the access device to a second configuration having an enlarged cross-sectional area at the distal portion spanning at least a portion of the multiple vertebrae, and performing various surgical procedures, such as decompression and fixation procedures, through the access device in order to provide a larger working area while reducing the amount of trauma experienced by the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the invention of Mathews further comprising the steps of performing a multi-level fixation procedure in view of Haider, advancing a decompression tool into the surgical site to perform a decompression procedure on the vertebrae in view of Foley, and inserting an access device in a first configuration through an incision of the skin until a distal portion is located adjacent the spine, actuating the access device to a second configuration having an enlarged cross-sectional area at the distal portion spanning at least a portion of the multiple vertebrae, and performing the surgical procedures through the access

device in view of Davison in order to fix multiple joints of the spine, to reduce pressure on the spinal cord, and to provide a larger working area while reducing the amount of trauma experienced by the patient.

Regarding the fixation system fasteners and an elongated member, Mathews discloses a method of treating the spine via a posterior approach comprising placing a fusion device in an intervertebral disc space between a first vertebra and a second vertebra in combination with a spinal fixation system, wherein the spinal fixation system includes fasteners in each vertebrae and an elongate plate member coupled to the fasteners in order to immobilize the spinal segments during fusion of the spinal segments. Haider teaches a method of treating the multiple spinal segments of the spine via a posterior approach comprising fusing the segments of the spine in combination with a spinal fixation system (see column 1 lines 13-17), wherein the spinal fixation system includes at least one fastener inserted into each vertebral body being immobilized and attaching an elongated member to the fasteners, wherein the fasteners includes a screw and a U-shaped housing that receives the head, i.e. joint, of the screw and the elongate member and the joint allows movement of the housing relative to the screw to orient the elongate member with respect to the housing in order to immobilize the spinal segments during fusion of the spinal segments (column 1 lines 13-17). Because both Mathews and Haider teach methods of treating the spine including the use of a spinal fixation system, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one spinal fixation system

with the other in order to achieve the predictable results of immobilizing the spinal during fusion of the spinal segments.

Response to Arguments

4. Applicant's arguments filed 04/03/2009 have been fully considered but they are not persuasive. The applicant's argument that the Mathews reference teaches away from the combination is not persuasive. The applicant argues that the Mathew reference discloses a device comprising a fixation system placed above the muscles and below the skin, and that using a multi-level rod/screw fixation system of Haider and the expandable insertion cannula of Davidson teaches away from the less traumatic minimally invasive method of Mathews. First, Mathews discloses a minimally invasive method of using a device comprising a plate/screw fixation system attached to the vertebra placed above the muscles of the spine and below the skin of the patient, wherein the primary function of the method/device is to stabilize adjacent vertebral bodies during fusion of the adjacent vertebral bodies. Haider discloses a method of using a device comprising a rod/screw fixation system attached to the vertebra, wherein the primary function of the method/device is to stabilize adjacent vertebral bodies during fusion of the adjacent vertebral bodies. It has been held that it is obvious to one having ordinary skill in the art to substitute functional equivalents, i.e. substitute the plate/screw fixation system with the rod/screw fixation system, to achieve predictable results, i.e. to stabilize adjacent vertebral bodies during the fusion of the vertebral bodies. Davison discloses a minimally invasive method of accessing the spine using a device comprising an expandable cannula to access the vertebra through a small incision, wherein the

second end of the cannula expands near the surface of the vertebrae (see Figure 5) to provide an expanded workspace below the surface of the skin while minimizing the size of the incision needed to perform the procedure and minimize the trauma experienced by the patient. Both Mathews and Haider disclose a method of using a fixation system to stabilize adjacent vertebral bodies during fusion and both Mathews and Davison disclose a method of minimally invasively performing a spinal procedure. Therefore, the examiner believes that the rejection of claims 20-29 under 35 U.S.C. 103(a) is proper and that the Mathews reference does not teach away from the proposed combination of reference presented by the examiner. The examiner has not provided any new grounds of rejection making this office action **FINAL**.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775